UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

DATE:

SUBJECT: Science Review of Registrant's Response to Deficiencies in Tolerance Petition 1F7920, Intended to Expand the Use of 1,4-Dimethylnaphthalene to Include Use on All Root and Tuber Vegetables (Crop Group 01) and Bulb Vegetables (Crop Group 03); Label Amendments for 67727-1, -3 and -4 Upon Tolerance Amendment Approval

Type of Data Review:	Human Health
Decision Number:	454569
DP Number:	402776
EPA Reg. Numbers:	1F7920 (Tolerance), 67727-1, -3, -4 (Label Changes)
Chemical Class:	Biochemical
PC Code:	055802
Tolerance Exemption:	40 CFR 180.1142
MRID Nos.:	

FROM: Russell S. Jones, Ph.D., Senior Biologist /s/ 06/21/2012
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: Colin Walsh, M.S., Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

In response to a request for additional information, Technology Sciences Group, Inc., on behalf of 1,4Group, Inc., has submitted a response to deficiencies identified by the Agency in an application to amend the established exemption from the requirement of a tolerance for residues of 1,4-Dimethylnaphthalene (1,4-DMN). The current tolerance exemption applies only to post-harvest use on potatoes. The submitted amendment sought to include an exemption from the requirement of a tolerance for all root and tuber vegetables (EPA Crop Group 01) and all bulb vegetables (EPA Crop Group 03). The established tolerance exemption was supported by a full set of acceptable acute toxicity ("6-pack") data (MRIDs 43082510 thru -15), mutagenicity data (MRIDs 43082416 thru -18, 46577001), and two residue studies conducted on potatoes (MRIDs 43266803 and 43594501). There is also a 90-day oral toxicity study (MRID 46316806) on file with the Agency. In addition, the following studies were previously submitted for review and deemed ACCEPTABLE: Dermal Sensitization using the Local

Lymph Node Assay (LLNA) method (MRID 48590902), Prenatal Developmental Toxicity (MRID 48590903), Unscheduled DNA Synthesis (MRID 48590904), Skin Absorption (MRID 48590905), Reproduction and Fertility Effects (MRID 48590906), and Carcinogenicity (MRID 48590907). Finally, the applicant submitted a document entitled, "Summary of the natural occurrence of 1,4-DMN in crops" (MRID 48653101) and a "GC/MS method for specific identification and confirmation of 1,4-DMN in plant material" (MRID 48653102).

In response to deficiencies identified in the Memorandum from G. Burnett to C. Walsh (dated 3/16/2012), the applicant submitted additional information (MRID 48810901), that essentially reiterates previously submitted toxicity studies and other information used to support the current tolerance exemption for potatoes (40 CFR 180.1142).

RECOMMENDATIONS AND CONCLUSIONS

1. The current exemption from the requirement of a tolerance for 1,4,-DMN, listed at 40 CFR 180.1142, includes potatoes only (post harvest use to inhibit sprouting). An expansion to include the entire root and tuber vegetable crop group (EPA Crop Group 01) is ACCEPTABLE. Specifically, the residue data on file for potatoes may be bridged to all other vegetables in this crop group, as established by the Agency, if the use pattern remains the same.

2. An expansion of the exemption from the requirement of a tolerance for 1,4-DMN to include bulb vegetables (EPA Crop Group 03) is upgraded to ACCEPTABLE (see Conclusions 3a, 3b, & ????? below).

3a. The residue data on file for potatoes is not representative of the members of the bulb vegetable crop group and, as stated in the Agency's Oct 20, 2012, letter to the applicant, may not be bridged to support an exemption for this crop group (but see Conclusion 3b).

3b. The registrant is requesting a Tolerance Exemption. Tolerance Exemptions do not typically require the submission of residue data, unless the Agency does not have sufficient information to assure human health and safety when humans are exposed to the active ingredient via dietary exposure.

3c. The Agency has determined that sufficient toxicity information exists to support expansion of the Tolerance Exemption to support bulb vegetables (EPA Crop Group 03) (see Conclusions 4 & 5; and the Memorandum from G. Burnett to C. Walsh, dated 03/16/2012. Therefore, except for the residue study (see Conclusion 3a), information, studies, and data used to support the expansion of the Tolerance Exemption (40 CFR 180.1142) for 1,4,-DMN on all root and tuber vegetable crops (EPA Crop Group 01) can be bridged to support the expansion of the Tolerance Exemption to include all bulb vegetables (EPA Crop Group 03).

4. Six toxicity studies were submitted in support of this were submitted and reviewed in support of the original action and deemed ACCEPTABLE by the Agency to support the expansion of the current Tolerance Exemption to include all root and tuber vegetables in Crop Group 01 (see Memorandum from G. Burnett to C. Walsh, dated 03/16/2012).

5. Two studies were submitted containing information on the natural occurrence of 1,4-DMN in various crops, although no information was available specifically in regard to 1,4-DMN levels in bulb vegetables (EPA Crop Group 03). Therefore, these studies were considered SUPPLEMENTAL, but useful in supporting the argument that 1,4-DMN is naturally-occurring in a wide variety of plants

NO DERS WERE WRITTEN FOR THIS REVIEW

cc: R. S. Jones, BPPD, C. Walsh, BPPD Science Review File, M. Xue/IHAD/ARS:
Russell S. Jones, Ph.D., Senior Biologist, FT. OPY-S: 06/21/2012